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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,924	10/31/2001	Shin-ichi Hashimoto	P21252	8540

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER
MARX, IRENE

ART UNIT	PAPER NUMBER
1651	6

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,924	HASHIMOTO ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application should be reviewed for errors. Error occurs, for example, in the spelling of "*Gordona*" throughout the specification and claims. The correct name appears to be *Gordonia.*

Claims 1-9 are being examined on the merits.

Claim 7-9 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention .

The written disclosure is incorrect and claims 7-9 are vague, indefinite and confusing in that the names of the species of bacteria and the indicated ATCC numbers do not correspond. At least ATCC 7005 is now indicated to be *Corynebacterium hoagii;* ATCC 21387 is now indicated to be *Brevibacterium sterolicum;* ATCC 21430 is now indicated to be *Nocardia sp.*; ATCC 19240 is now indicated to be *Brevibacterium thiogenitalis;* ATCC 953, is now indicated to be *Exiguobacterium acetylicum* ; ATCC 8363, is now indicated to be *Desemzia incerta*; ATCC 186 is now indicated to be *Kocuria rosea*; ATCC 15921 is now indicated to *be Brevibacterium lyticum*; ATCC 15098, is now indicated to be *Sphingopyxis terrae*, and, ATCC19067 is now indicated to be *Rhodococcus rhodochrous* sp.. In addition the nature and identity of the microorganisms deposited or obtained elsewhere cannot be readily ascertained.

Correction is required.

Rejections under 35 U.S.C § 112

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention requires the use of various strains which bear the designation JCM, IFM and IFO. It is not clear if the written description is sufficiently repeatable to avoid the need for a

deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It is not clear if the deposits of these strains, if any, meet all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the

availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the requirement that the cultured microorganism "shows no hyphal growth". This limitation is confusing and inconsistent with the written disclosure, since the genera, species and strains of microorganisms recited in dependent claims 6-9 show hyphal growth at least to some extent. All of the genera recited, except *Shingomonas* are *Actinomycetes*. The genera *Mycobacterium, Corynebacterium, Brevibacterium, Rhodococcus, Gordonia, Arthrobacter, Micrococcus,* and *Cellulomonas* all belong to the *Actinomycetes*. Hyphal growth for these microorganisms is acknowledged in the specification at page 2, wherein it is stated that *Actinomycetes* "grow with filamentous forms by elongating hyphae".

Claim 5 is confusing in that it recites as the last item that the treated product of the culture is a treated product which is "treated cells". This appears redundant.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the

inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kranjc *et al.* in light of the ATCC website. (www.ATCC.org.).

The claims are directed to a process of hydroxylation using a microorganism that does not sporulate and which shows no hyphal growth, and in particular to the use of certain genera, species and strains of microorganisms.

Kranjc *et al.* teach of process of hydroxylation using a strain of *Amycolatopsis orientalis* ATCC 19795. This strain was deposited as *Streptomyces orientalis,* and other strains of this species are or have been classified as *Nocardia orientalis.* Inasmuch as at least strain ATCC 21430 is now classified as *Nocardia sp..* and in view of the inconsistencies and ambiguities in the instant record, it is submitted that the process is anticipated by the reference. See, e.g., ATCC printout, which adequately demonstrates that strains of *Nocardia* are now classified as variously as *Rhodococcus, Gordonia, Nocardiopsis, Streptomyces, Actinomadura, Amycolatopsis,Mycobacterium, Pseudonocardia, etc.*

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed process would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Davis *et al.* in light of the ATCC website (www.ATCC.org.)

The claims are directed to a process of hydroxylation using a microorganism that does not sporulate and which shows no hyphal growth, and in particular to the use of certain genera, species and strains of microorganisms.

Davis *et al.* teach of process of hydroxylation using various strains of bacteria including *Amycolata autotrophica* ATCC 35024. This strain is now classified as *Pseudonocardia autotrophica,* but was deposited as *Nocardia autotrophica.* Inasmuch as at least strain ATCC 21430 is now classified as *Nocardia sp.* and in view of the inconsistencies and ambiguities in the instant record, it is submitted that the process is anticipated by the reference. See, e.g., ATCC printout), which adequately demonstrates that strains of *Nocardia* are now classified as variously as *Rhodococcus, Gordonia, Nocardiopsis, Streptomyces, Actinomadura, Amycolatopsis,Mycobacterium, Pseudonocardia, etc.*

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed process would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Demain *et al.* U.S. Patent No. 5,942,423 in light of the ATCC website (www.ATCC.org.)

The claims are directed to a process of hydroxylation using a microorganism that does not sporulate and which shows no hyphal growth, and in particular to the use of certain genera, species and strains of microorganisms.

Demain *et al.* teach of process of hydroxylation using a strain of *Actinomadura,* which is an *Actinomycete* closely related to the disclosed and claimed strains (See, e.g., Examples). Inasmuch as at least strain ATCC 21430 is now classified as *Nocardia sp.* and in view of the inconsistencies and ambiguities in the instant record, it is submitted that the process

is anticipated by the reference. See, e.g., ATCC printout), which adequately demonstrates that strains of *Nocardia* are now classified as variously as *Rhodococcus, Gordonia, Nocardiopsis, Streptomyces, Actinomadura, Amycolatopsis, Mycobacterium, Pseudonocardia, etc.*

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed process would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Okazaki *et al.* in light of the ATCC website. (www.ATCC.org.).

The claims are directed to a process of hydroxylation using a microorganism that does not sporulate and which shows no hyphal growth, and in particular to the use of certain genera, species and strains of microorganisms.

Okazaki *et al.* teach of process of hydroxylation using a strains of *Nocardia* (See, e.g., page 1176, paragraph 1). Inasmuch as at least strain ATCC 21430 is now classified as *Nocardia sp.*. and in view of the inconsistencies and ambiguities in the instant record, it is submitted that the process is anticipated by the reference. See, e.g., ATCC printout, which adequately demonstrates that strains of *Nocardia* are now classified as variously as *Rhodococcus, Gordonia, Nocardiopsis, Streptomyces, Actinomadura, Amycolatopsis, Mycobacterium, Pseudonocardia, etc.*

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the

claimed process would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Primary Examiner
Art Unit 1651